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APPLICATION NUMBER: ***60/555,977***
FILING DATE: ***March 25, 2004***

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

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PTO/SB/16 (01-04)
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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
ELAN	ZIV MD	RAMAT GAN ISRAEL

Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

A MULTIDIMENSIONAL VAGINAL DEVICE FOR THE TREATMENT & PREVENTION OF URINARY INCONTINENCE

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☐ Customer Number:

OR

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ENCLOSED APPLICATION PARTS (check all that apply)

☐ Specification Number of Pages 8
☐ Drawing(s) Number of Sheets 7
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number _____
☐ Other (specify) _____

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☑ Applicant claims small entity status. See 37 CFR 1.27.
☑ A check or money order is enclosed to cover the filing fees.
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FILING FEE Amount ($): $80

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

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Respectfully submitted,

SIGNATURE _____ Date 21.3.04

TYPED or PRINTED NAME DR. ELAN ZIV MD REGISTRATION NO. _____ (if appropriate)

TELEPHONE +972-53-569928 Docket Number: _____

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This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 80

Complete if Known	
Application Number	
Filing Date	MARCH 23, 2004
First Named Inventor	Dr Elan Ziv
Examiner Name	
Art Unit	
Attorney Docket No.	

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	80

SUBTOTAL (1) ($) 80

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below	Fee Paid
Total Claims		-20** =	X	=
Independent Claims		- 3** =	X	=
Multiple Dependent				=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

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FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($)

SUBMITTED BY

(Complete (if applicable))

Name (Print/Type)	Dr Elan Ziv MD	Registration No. (Attorney/Agent)		Telephone	+97237369261
Signature				Date	March 14, 2004

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A MULTI-DIMENSIONAL VAGINAL DEVICE FOR THE TREATMENT AND PREVENTION OF URINARY INCONTINENCE IN FEMALES

The present invention relates generally to the field of treatment of urinary incontinence in female patients. More specifically, the present invention relates to a disposable device for use in the treatment of urinary incontinence in women. The invention describes a vaginal disposable device which is inserted and removed in a no-self-touch technique, by the patient herself, using a disposable applicator.

Inventor: Dr Elan Ziv, MD OBGYN, Urogynecologist

Background of the Invention

Urinary incontinence is a widespread problem among females. It is estimated that up to 50% of women occasionally leak urine involuntarily, and that approximately 25% of woman will seek medical advice at some point in order to deal with the problem. Stress incontinence, the most common type of urinary incontinence, refers to the involuntary loss of urine resulting from abdominal pressure rise, occurring during exercise, coughing, sneezing, laughing, etc. When stress incontinence occurs, it is usually the result of the abnormal descent of the urethra and bladder neck below the level of the pelvic floor. While many different factors may contribute to the development of stress incontinence, it is most prevalent among women ages 35-65 and those who have had multiple vaginal deliveries. Stress incontinence is both aggravating and unpleasant for women, and it can also be embarrassing. Many women wear sanitary pads or diapers in order to deal with incontinence, though this is not a real solution to the problem and it can be very inconvenient and unreliable. Surgical treatment may involve securing the paraurethal tissues to the periosteum of the pubic bone or the rectus facia in order to elevate the bladder neck above the pelvic floor and thereby distribute pressure equally to the bladder, the bladder neck, and the mid-urethra. Recently, a procedure known as "TVT" ("Tension Free Vaginal Tape") was developed, in which a mesh tape is implanted underneath mid-urethra, creating a hammock on which the urethra may kink during physical effort.

However, surgery is only suitable for severe cases, and the majority of women experiencing incontinence do not need surgical solutions.

One modality of non-surgical treatment involves the use of devices that are inserted into the vagina, either by a medical practitioner or by the woman herself. Most devices are designed to apply pressure against the bladder neck so as to inhibit or completely block the flow of urine through the urethra. A variety of such devices are known in the art. For example, refer to U.S. Patent No. 5,618,256 to Reimer, entitled, "Device for Arrangement in the Vagina for Prevention of Involuntary Urination with Females and an Applicator for use in Insertion of the Device;" U.S. Patent No. 5,785,640 to Kresch, entitled "Method for Treating Female Incontinence;" U.S. Patent No. 4,920,986 to Biswas, entitled, "Urinary Incontinence Device;" U.S. Patent 5,417,226 to Juma, entitled, "Female Anti-Incontinence Device;" U.S. Patent No. 5,386,836 to Biswas, entitled, "Urinary Incontinence Device;" and U.S. Patent No. 5,007,894 to Enhorning, entitled, "Female Incontinence Device."

The existing non-surgical incontinence devices suffer from numerous drawbacks:

- A number of devices are constructed so as to completely block the urethra and thus they need to be removed or collapsed in order to allow the woman to urinate, an inconvenience for the woman wearing the device.
- To overcome this drawback, vaginal devices have been developed having specialized shapes that do not completely block the bladder neck. These devices tend to be large, uncomfortable, and intrusive. They also tend to cause irritation or soreness to the vagina.
- Such devices are expensive to manufacture, and therefore, they are designed to be re-usable and/or to remain in the vagina for an extended period of time. Such devices are normally made from large bodies of resilient material, such as plastic or hard rubber, in order to preserve their functioning for the required amount of time.
- Most devices known in the art also tend to be difficult or painful to insert and/or remove. In order to correctly inhibit urine flow, the device needs to be properly positioned in the vaginal canal. As stated previously, a doctor may be required to properly position the device.

- In cases where a doctor has to insert the device, the device is adapted for remaining in the vagina for a prolonged period of time. When positioned in the vagina for an extended period of the time, the device may cause vaginal infections, necrosis, or bleeding.
- The device may block or inhibit the flow of normal body secretions through the vagina, and may cause inflammation of the vagina and a foul-smelling discharge.
- In cases where the device is designed to be inserted by the woman herself, the device often has to be removed, cleaned, and then re-inserted after a predetermined number of hours.

All vaginal devices so far described or marketed have at least one of the limiting features described above. No vaginal device for controlling urinary incontinence has so far been successfully marketed and used by the woman herself. There is a need for a device for controlling involuntary urination that is disposable, easy and comfortable for a woman to use, that works effectively and reliably, and that is completely sanitary and hygienic.

The Invention

The present invention provides a device for the treatment of urinary incontinence females. The device of the present invention is adapted to be disposable, worn only for a maximum of 16 hours and then discarded and replaced with a new device (if needed). The device of the present invention is simple and easy to use, and is inserted effortlessly in the same user-friendly and familiar manner that a tampon is inserted into the vagina during menstruation. As opposed to large and intrusive devices of the prior art, the device of the present invention is comfortable, and, once inserted, the woman need not think about it again until it is removed.

When involuntary urination occurs, it is usually the result of the abnormal descent of the bladder neck and the urethra into a low position, away from the intra-abdominal pressure system. This "hypermobility" is the result of some injury to the support mechanism which normally keeps the urethra and the bladder neck in a raised position, along the backside of the pubic bone. The lowering of the bladder neck and the urethra that occur, for example, when a woman coughs, sneezes, or laughs, causing involuntary leakage of urine. The device of the present invention is designed so as to provide a "cradle" or shelf-like support to the urethra whenever the urethra descends momentarily, so as to prevent the leakage of urine. The device does not put pressure against the urethra or the bladder neck, but only provides support when there is a rise in abdominal pressure.

The present invention relates to a disposable device for the prevention of involuntary urination in females, adapted for being inserted into the vagina, comprising;

(a) an internal support structure

(b) a cover covering said internal support structure and comprised of a flexible material, and;

(c) an applicator coupled to the internal support structure and the cover for facilitating insertion of the device into the vagina;

The main device and the cover are adapted for forming a cradle support for the mid-urethra following insertion of the device into the vagina so as to prevent involuntary urination while allowing for voluntary urination.

The invention will now be described with reference to accompanying drawings:

FIG. 1A is a side view of the internal support structure.

FIG. 1B is a top view of the internal support structure

FIG. 1C is a perspective view of the internal support structure

FIG. 2A is a side view of the extender.

FIG. 2B is a top view of the extender

FIG. 2C is a perspective view of the extender

FIG. 3A is a sectional side view of the internal support structure at rest

FIG. 3B is a sectional side view of the extended internal support structure

FIG. 4A is a perspective view of the covering

FIG. 4B is a perspective view of the main device inside the covering.

FIG. 5 is a perspective view of the applicator.

FIG. 6 is a sectional view of the invention within the applicator

FIG.7 is a side view of the female pelvis.

The core of the device is a one prolonged embodiment (FIG 1A) which has three distinct parts:

1. A top section (8) which serves as the "anchoring" element, for stabilizing the device within the vagina,
2. A bottom section (10) which serves as the "supporting" element, generating mid-urethral support,
3. An intermediate section (9) which connects top & bottom elements. Along its longitudinal axis, there is a central tunnel (16) which connects top & bottom sides, allowing for the passage of the extending insert.

Each element of the device (FIG 1A+B+C) has 4 flexible arms. These arms of the anchoring element (11), force the device to remain in situ within the vagina, unable to move inwards or outwards, or to rotate. This occurs as a result of the special tendency of vaginal walls to collapse and form an occluded lumen. The flexible arms of the device cause "tenting" of the walls on top of them with resultant sagging of the walls around the intermediate section, thereby stabilizing the device. The arms of the supporting element

(13) cause elevation of the tissues around mid-urethra, acting as a hammock. This hammock supports mid-urethra in a tension free manner, much like the TVT operation.

The support element has between its arms an extender (FIG 2A+B+C) which is a separate unit. This extender has two distinct parts: the tucker (14) with its enlarged arrow head (15), arising from the flat bottom plate (12). This flat plate is made of flexible material (such as silicone, polyurethane, etc) which enables easy folding into the applicator. The tucker is forcefully pushed into the central tunnel, thereby allowing for its anchoring to the device.

In its resting position (FIG 3A), the extender does not influence expansion of the arms. The plate is within the space between the arms, without changing dimensions of the support element. FIG 3B shows the same device after forward pushing of the extender. The plate is now much closer to the intermediate section of the device, thereby forcefully spreading the arms, enlarging the diameter of the supporting element. This is essential for creating a device with changing dimensions for treating patients with various vaginal sizes.

The plate has another distinct feature, besides changing diameters. It also serves as a support element for the arms, mainly when a larger diameter is needed, to negate the forces from the vaginal walls.

The tucker may be pushed in to different depths along the central canal thereby allowing for a wide range of diameters of the support element. The wider arrow head ensures a secured placement due to its wider diameter.

The device and the extending unit will be assembled together and introduced into the cover (FIG 4).

The cover (FIG 4A) is made of a flexible smooth mesh material (17) designed as small sack with a string (18). FIG 4B shows the device (20) within the tightly closed mesh cover (22). The cover allows for:

- Reduction of the friction between vagina and the device during insertion & removal.
- Reduction of the friction between the applicator and the device during insertion.
- Pulling the string causes straightening of the cover, straightening of the vaginal walls, allowing for an easy and smooth removal of the device from the vagina.

- Pulling the string causes the arms to fold slightly towards the midline, thereby reducing its size, allowing for an easy and smooth removal of the device from the vagina.
- The mesh of the cover, being stretched between the arms of the device, also serve as a hammock. In a woman who leaks urine during a stressful event (when abdominal pressure rises during coughing, sneezing, etc.), the urethra sags down but meets the hammock in its mid part. That also causes an elevation of the intra urethral pressure with resultant urinary continence.

The applicator serves for insertion of the device into the vagina (FIG 5), as is done when inserting a regular menstrual tampon. The device is kept within the wider part (26) that is inserted into the vagina. When pushing the plunger (28), the device is pushed through the flower like opening (24), allowing for its immediate action once the applicator is removed from the vagina. The string (32) is visible, protruding out of the opening of the plunger (30).

When the device is still within the applicator (FIG 6), its flexible arms (34) converge towards the midline, allowing for the small dimensions and its insertion via a small diameter applicator. After insertion (FIG 7), the flexible arms of the device gain their pre-intended tension, enlarge the diameter of the device (46) within the vagina (48), anchoring itself under the bladder (40) between the uterine cervix (36) and the pubic bone (38), supporting mid-urethra (42). The string protrudes out of the vaginal introitus (44), as with the regular menstrual tampon, allowing for removal.

The invention has in its basic concept the following features:

- Being a disposable device.
- Insertion of the device is always with an applicator.
- Easy & comfortable insertion and removal.
- Being comfortable to wear.
- Being hygiene & odorless
- Being a familiar procedure to most female patients – as inserting a menstrual tampon.
- Being inserted by the patient herself, in a no-self-touch technique, with a disposable inserter.
- Being removed by the patient herself, in a no-self-touch technique, with the device collapsing and becoming of small size for painless removal.
- Being of high availability, easy to get everywhere, sold as an Over the Counter (OTC) device.
- Being of low cost.
- Having complete confidentiality, as with the use of menstrual tampons.
- Having the ability to be removed instantly when needed.
- No blockage of vaginal discharge.
- Wide range of diameters

Alternative embodiments of the invention.

- It may be manufactured in different sizes
- It may be made of many flexible materials, such as silicone, polyurethane, etc.
- It can have more or less than 4 arms.
- The angle between the arms may be changed.

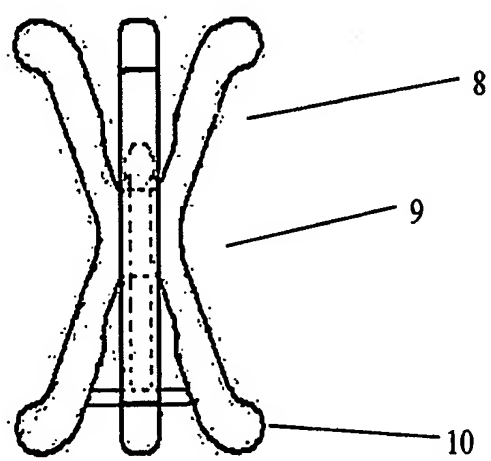

FIG. 1A

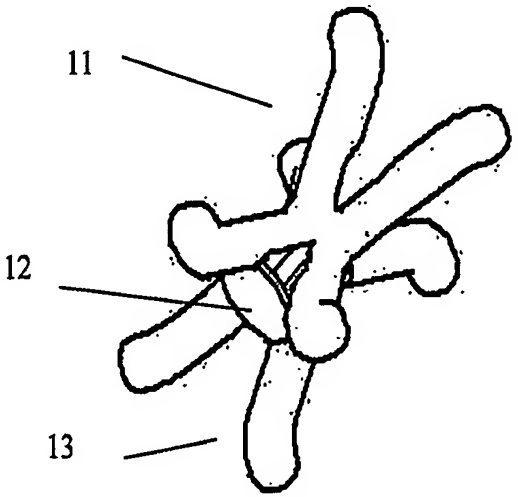

FIG. 1C

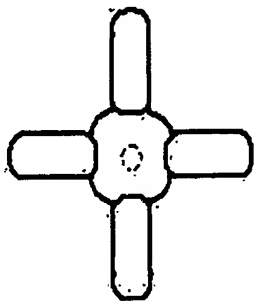

FIG. 1B

A multi-dimensional vaginal device for treatment & prevention of female urinary incontinence"
Dr Elan Ziv, MD OBGYN, Urogynecologist

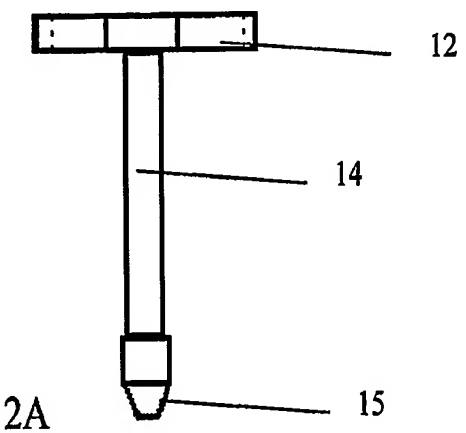

FIG. 2A

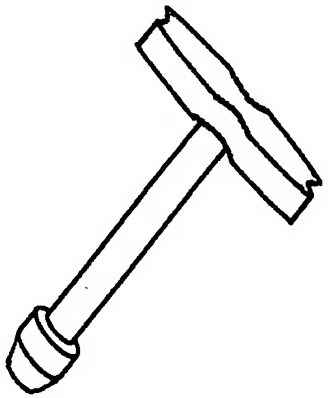

FIG. 2B

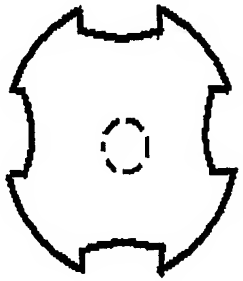

FIG. 2C

A multi-dimensional vaginal device for treatment & prevention of female urinary incontinence"
Dr Elan Ziv, MD OBGYN, Urogynecologist

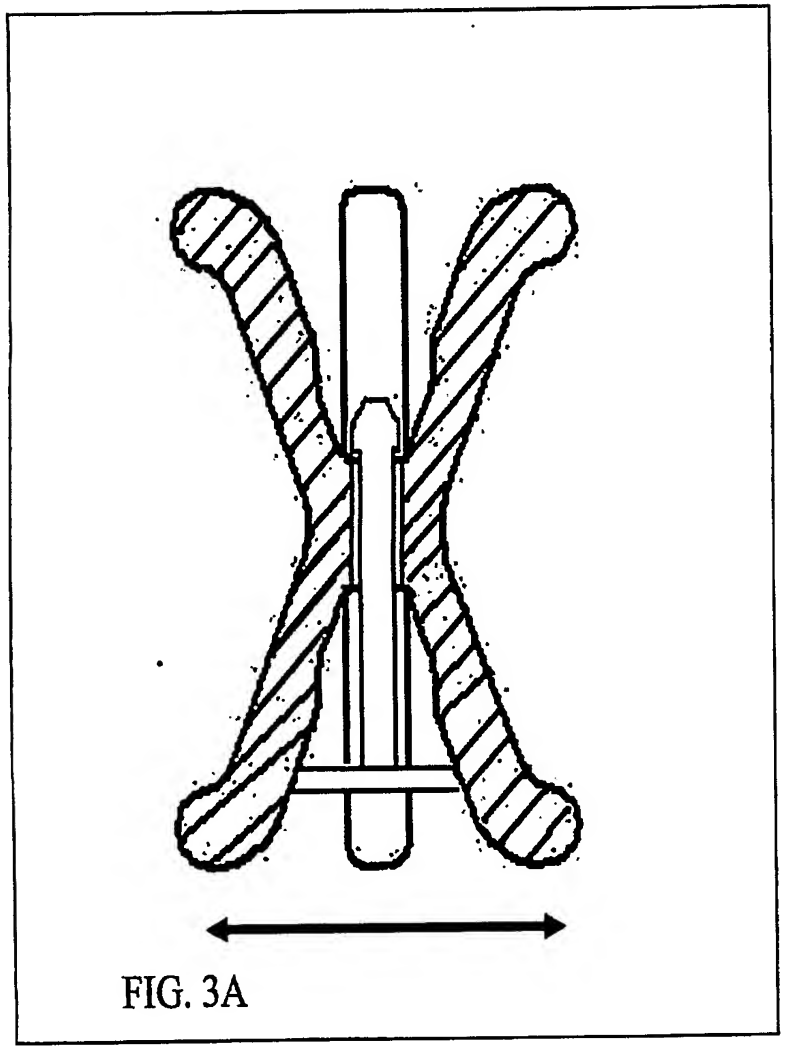

FIG. 3A

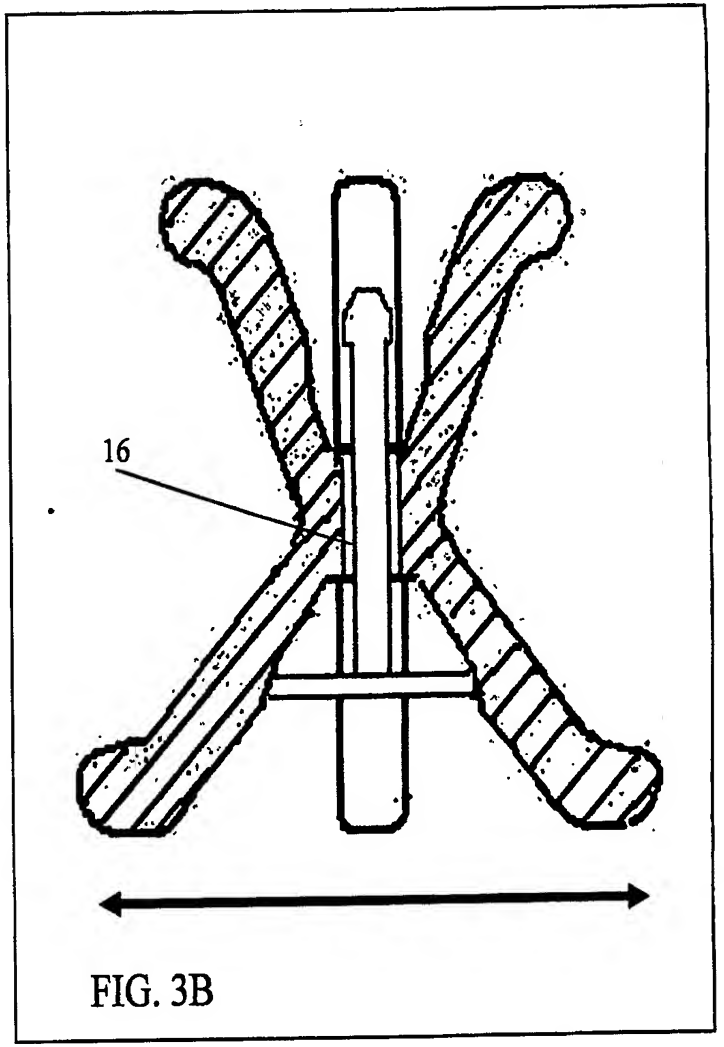

FIG. 3B

A multi-dimensional vaginal device for treatment & prevention of female urinary incontinence"
Dr Elan Ziv, MD OBGYN, Urogynecologist

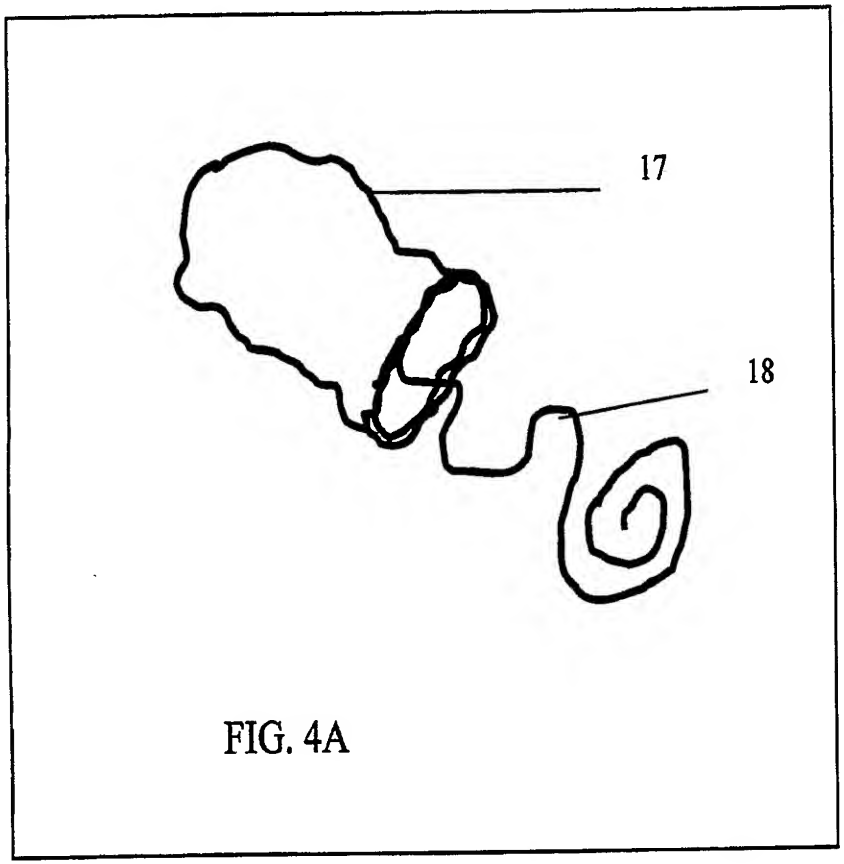

FIG. 4A

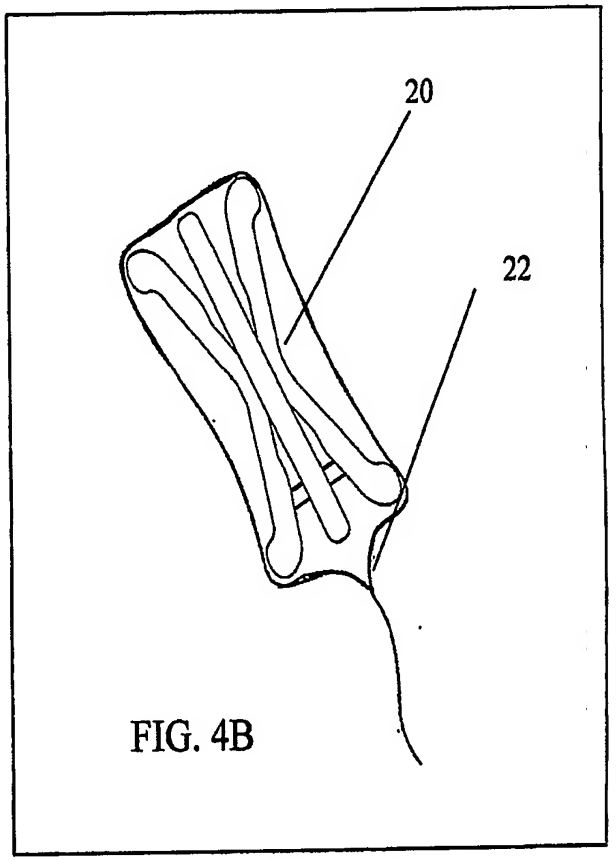

FIG. 4B

A multi-dimensional vaginal device for treatment & prevention of female urinary incontinence"
Dr Elan Ziv, MD OBGYN, Urogynecologist

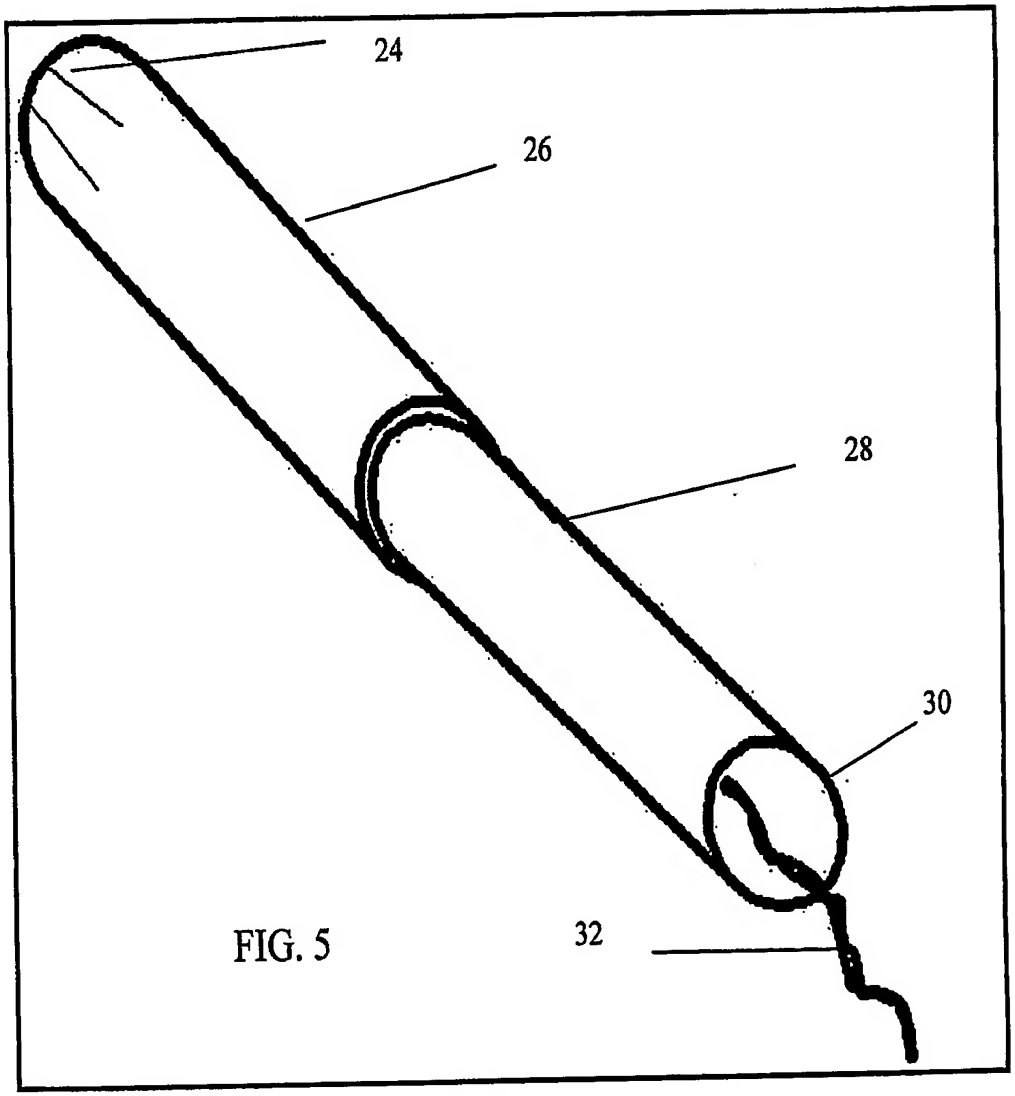

FIG. 5

A multi-dimensional vaginal device for treatment & prevention of female urinary incontinence"
Dr Elan Ziv, MD OBGYN, Urogynecologist

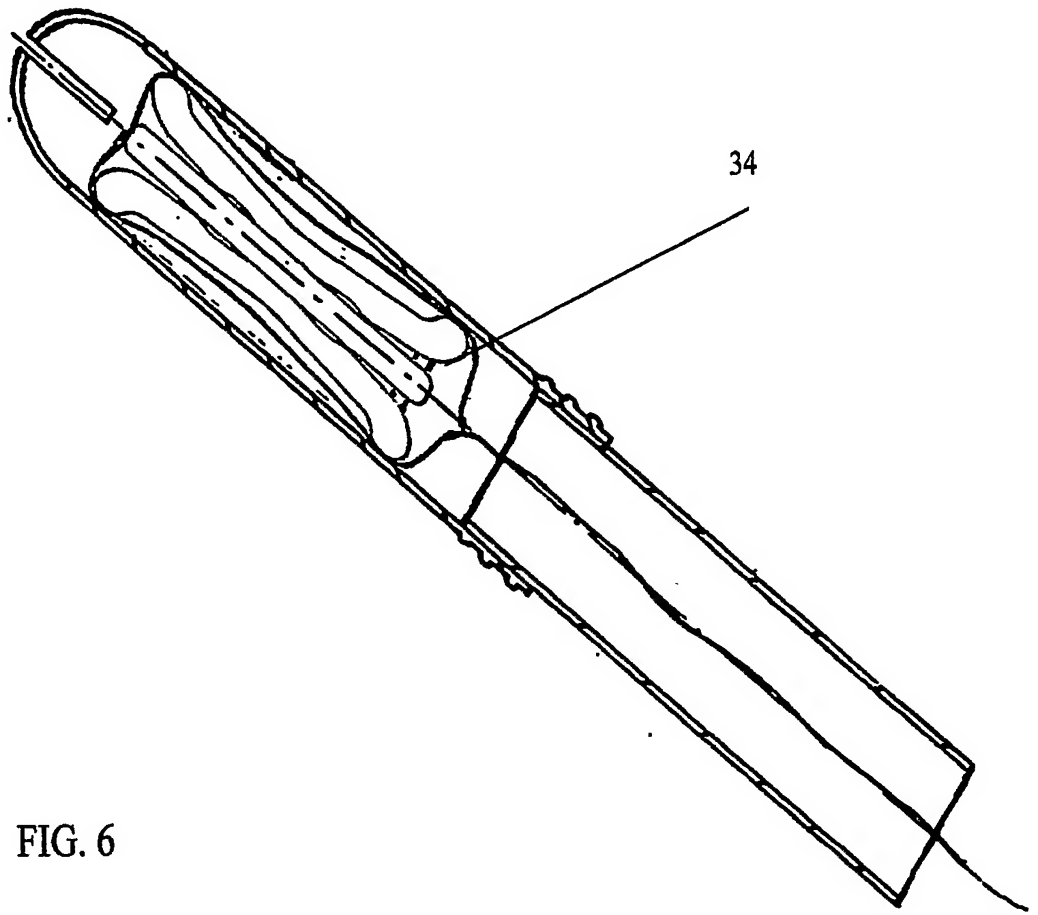

FIG. 6

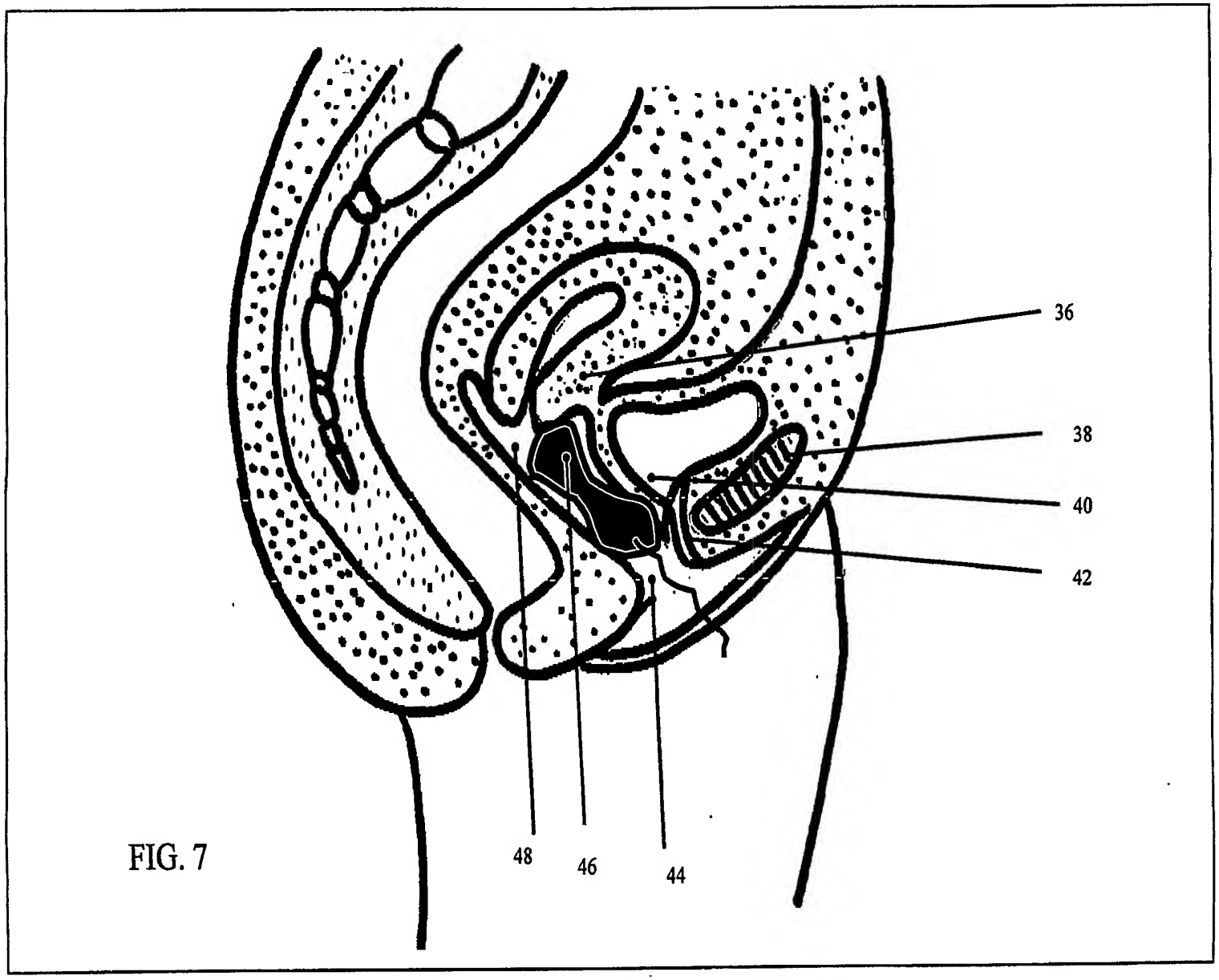

FIG. 7

A multi-dimensional vaginal device for treatment & prevention of female urinary incontinence"
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